UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

UNITED STATES OF AMERICA ex rel. LORNE HOLLAND and MICHELLE TAYLOR,

Plaintiffs-Relators,

v. Case No. 6:17-cv-1592-Orl-37GJK

DAVITA, INC.; TOTAL RENAL LABORATORIES, INC.; and DVA LABORATORY SERVICES, INC.,

Defendants.

ORDER

Defendants DaVita, Inc. ("**DaVita**"), Total Renal Laboratories, Inc. ("**Total Renal**"), and DVA Laboratory Services, Inc. ("**DVA**") move to dismiss Relators Lorne Holland's ("**Holland**") and Michelle Taylor's ("**Taylor**") Second Amended Complaint (Doc. 57 ("**Complaint**")). (Doc. 74 ("**Motion**").) Relators responded (Doc. 79) and Defendants replied (Doc. 83). On review, the Motion is denied.

I. BACKGROUND[1]

DaVita is a leading provider of dialysis services in the United States. (Doc. 57, ¶ 9.) Dialysis patients rely on lab testing to determine the stage of their disease and how to

[1] These facts are presented in the light most favorable to Relators with factual allegations in the Complaint taken as true. *See Hill v. White*, 321 F.3d 1334, 1335 (11th Cir. 2003).

properly treat it. (*Id.* ¶ 88.) To provide these lab services, DaVita depends on two licensed clinical labs wholly owned, managed, and controlled by DaVita: Total Renal and DVA. (*Id.* ¶¶ 11–15.) Defendants used Total Renal and DVA, both in Florida, for all of DaVita's nation-wide testing needs because of favorable state tax breaks. (*Id.* ¶¶ 111, 253.) As a result, Defendants must transport medical samples from where they are collected throughout the United States, over long distances, to the Florida labs. (*Id.* ¶ 111.)

Medicare Part B covers testing and treatment for dialysis patients. (*Id.* ¶¶ 23–25.) But tests are covered only when performed by a lab compliant with the Clinical Laboratory Improvements Amendments ("**CLIA**"). (*Id.* ¶¶ 26–27.) Participating providers, such as DaVita, must certify compliance with CLIA regulations and must notify Medicare of any changes affecting certification. (*Id.* ¶¶ 27, 32.) CLIA regulations require labs to follow established policies and procedures that ensure the "optimum integrity" of lab samples from the time of collection through the reporting of test results. (*Id.* ¶ 53.) Testing must follow the manufacturer's instructions and provide test results within the lab's stated performance specifications. (*Id.* ¶ 56.) CLIA requires labs who modify these pre-approved testing or storage methods to establish the accuracy and precision of the new methods. (*Id.* ¶ 60.) Adherence to CLIA regulations affects a lab's overall test performance, reliability, and accuracy—and failure to abide by these regulations can result in loss of federal funding. (*Id.* ¶¶ 62–64.)

DaVita possesses a CLIA certificate of accreditation and participates in Medicare Part B, filing claims for reimbursement for tests performed in its labs. (*Id.* ¶¶ 104, 106–

07.) Yet Defendants repeatedly violated CLIA regulations—to potentially tragic results. (*See id.* ¶ 114.) For example, specimens must be maintained under specific environmental conditions to ensure they do not deteriorate and produce inaccurate results. (*Id.* ¶ 112–14.) But DaVita transports specimens over long distances to Florida under poorly controlled environmental conditions. (*Id.* ¶ 111.) Refrigerated specimens, frozen specimens, and room temperature specimens are all shipped in the same box cross-country. (*Id.* ¶ 116.) And after they arrive, Defendant keep these same specimens at room temperature for extended times before testing. (*Id.* ¶¶ 116, 122–23.) Record-keeping is also deficient: Defendants fail to record transport and storage conditions and how long a specimen has been stored—and Defendants test specimens too old to be reliable. (*See id.* ¶¶ 115, 118–19.)

Other CLIA violations occur during testing. Defendants deviated from pre-approved test methods without performing method validations for these modifications, as required by CLIA regulations. (*Id.* ¶¶ 102–03, 129, 132, 136–37.) Defendants changed centrifuge times and forces, failed to timely separate samples into liquid and cellular portions, and didn't use the required but more expensive gel collection tubes. (*Id.* ¶¶ 137–39, 164–65.) Despite these CLIA violations and Defendants' inability to ensure the reliability or accuracy of the test results, Defendants submitted claims for reimbursement to Medicare. (*See, e.g.*, ¶¶ 130–134, 141–63, 171–204.)

Defendants hired Holland in 2014 as the Chief Laboratory Officer for Total Renal. (*Id.* ¶ 16.) He also served as Vice President of Operations and the CLIA Medical Director.

(*Id.*) Holland complained multiple times to his supervisors about Defendants' timeliness in testing specimens and concerns with specimen stability—but these concerns were ignored. (*Id.* ¶ 265) In February 2017, he discovered Defendants lacked validation studies on specimen stability for a new Hepatitis C RNA by PCR test, despite submitting reimbursement claims to the Government. (*Id.* ¶ 205.) Overcoming pushback from supervisors, Holland corrected the stability issues by using more expensive collection tubes and Defendants refunded the Government for prior improper tests. (*Id.* ¶ 206.) Defendants also switched to the more expensive test tubes for a similar test for HCV antibodies—but refunded no money. (*Id.* ¶ 207.)

Shortly after the Hepatitis C RNA by PCR issues were corrected, Holland was ostracized by his supervisor. (*Id.* ¶ 267.) Holland was forced to resign as CLIA Medical Director on March 20, 2017 but remained Vice President of Laboratories and the Chief Laboratory Officer. (*Id.* ¶ 266.) So Holland filed a formal complaint against his supervisor, prompting Defendants to issue Holland a written warning over regulation compliance. (*Id.* ¶¶ 267–70.) Defendants also required Holland to develop a comprehensive Standard Operating Procedures template as part of a punishing Corrective Action Plan. (*Id.* ¶¶ 267–70.) Holland complained about the lack of method validations to Keith Carrington, DaVita's Director of Corporate Compliance and David Van Wyck, the Vice President of Clinical Support Services. (*Id.* ¶ 272–73.) And he discussed his compliance concerns with Andrew Mohraz, DaVita's Associate General Counsel and Head of Investigations. (*Id.* ¶ 274.) On April 25, 2017, DaVita's Chief Medical Officer began

pressuring Holland to resign and one month later, Holland was escorted out of the lab and Dr. Van Wyck told him he was terminated without explanation. (*Id.* ¶¶ 277–78.)

Taylor, who took over for Holland as CLIA Medical Director in March 2017, witnessed Defendants' response to Holland's efforts to comply with CLIA regulations. (*Id.* ¶ 281.) On May 26, 2017, she told Dr. Van Wyck and Sharon Alpizar, DaVita's Director of People Services, she was unhappy with Holland's treatment—she also expressed serious concerns about the competencies of DaVita's medical technologist and requests by clinicians to change lab results. (*Id.* ¶ 282.) About a week later, Dr. Van Wyck and Ms. Alpizar informed Taylor she had ninety days to resign and, effective immediately, she was no longer responsible for quality assurance and safety. (*Id.* ¶ 283.) Taylor acquiesced, emailing Dr. Van Wyck her resignation notice on June 7 with a last day of September 4, 2017—but this wasn't enough. (*Id.* ¶¶ 284–86.) Defendants gave Taylor a verbal warning and an unreasonable Corrective Action Plan, just as they had with Holland; they also required all conversations with her supervisor to be witnessed and memorialized by email. (*Id.* ¶¶ 285–86.) And, on July 3, 2017, she was told to remain on-call but not come to the laboratory or attend meetings. (*Id.* ¶ 294.)

During this time, Taylor raised additional concerns with higher-ups at DaVita. Taylor met with Mr. Mohraz on June 23 and 26, 2017 to discuss DaVita's compliance issues, and informed Mr. Carrington she was concerned about DaVita's method validations. (*Id.* ¶¶ 287.) Taylor also raised method validation issues for peritoneal dialysate testing and was told by Defendants they wouldn't remedy these. (*Id.* ¶¶ 289–

91.) Faced with Defendants' resistance to her compliance efforts and their continued attempts to tarnish her record, Taylor moved her last day up to July 19, 2017. (*Id.* ¶ 293.)

Relators sued Defendants for False Claims Act ("**FCA**") violations, including the presentment of false claims, conspiracy, a "reverse" FCA claim, and retaliation. (*See* Docs. 1, 57.) The Government declined to intervene and the case proceeded *qui tam*. (Doc. 22.) Defendants now move to dismiss for failure to state a claim. (Doc. 74.) Briefing complete (Docs. 79, 83), the matter is ripe.

II. LEGAL STANDARDS

Under the minimum pleading requirements of the Federal Rules of Civil Procedure, plaintiffs must provide short and plain statements of their claims. *See* Fed. R. Civ. P. 8(a), 8(d), 10(b). If a complaint does not satisfy these minimum pleading requirements, is plainly barred, or otherwise fails to state a plausible claim, then it may be dismissed under Rule 12(b)(6). *See Ashcroft v. Iqbal*, 556 U.S. 662, 672, 678–79 (2009) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007)).

And, for claims of fraud or mistake, "a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other condition of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). Claims submitted under the FCA, must comply with the heightened pleading requirements of Rule 9(b). *U.S. ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1308–09 (11th Cir. 2002) (quoting 31 U.S.C. § 3729(a)). For an FCA claim, a plaintiff must plead "facts as to time, place, and substance of the defendants' alleged fraud, specifically the details of the

defendants' allegedly fraudulent acts, when they occurred, and who engaged in them." *Id.* at 1310 (internal quotation marks and citations omitted).

III. ANALYSIS

Defendants move to dismiss the Complaint. (Doc. 74.) Let's take each count in turn.

A. Presenting and Submitting False Claims (Counts I and II)

Relators claim Defendants are liable under the FCA for submitting Medicare reimbursement claims for inaccurate and unreliable tests they performed in violation of CLIA regulations. (Doc. 57, ¶¶ 298–310.) Defendants acknowledge Relators have properly pled CLIA violations but argue regulatory violations alone do not make testing reimbursement claims presented and submitted to the Government "false" under the FCA. (Doc. 74, pp. 13–22.) Relators respond Defendants are liable under the implied false certification theory. (Doc. 79, pp. 16–21.)

The FCA "imposes significant penalties on those who defraud the Government." *Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, 136 S. Ct. 1989, 1995 (2016) [hereinafter, *Escobar*]. Under the "implied false certification" theory, liability may attach "when the defendant submits a claim for payment that makes specific representations about the goods or services provided, but knowingly fails to disclose the defendant's noncompliance with a statutory, regulatory, or contractual requirement." *Id.* A defendant is liable only where the misrepresentation is "knowing" and "material." *Id.* at 1996. The FCA defines "material" as "having a natural tendency to influence, or be capable of

influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4); *see also Escobar*, 136 S. Ct. at 1996. "[S]tatutory, regulatory, and contractual requirements are not automatically material, even if they are labeled conditions of payment," because "billing parties are often subject to thousands of complex statutory and regulatory provisions." *Escobar*, 136 S. Ct. at 2001–02. Instead, courts must consider "whether noncompliance is 'minor or insubstantial' and amounts to 'garden-variety breaches of contract or regulatory violations,' or, conversely, whether the Government would have attached importance to the violation in determining whether to pay the claim." *Marstellar for use and benefit of U.S. v. Tilton*, 880 F.3d 1302, 1313 (11th Cir. 2018) (quoting *Escobar*, 136 S. Ct. at 2002–03). The standard is demanding—the FCA "is not an all-purpose antifraud statute." *Escobar*, 136 S. Ct. at 2003 (quotation marks and citation omitted).

Defendants' attempt to paint the alleged misrepresentations as mere regulatory violations is a version of legal Three-card Monte. (*See* Doc. 74, pp. 16–21.) Relators allege Defendants submitted claims for Government reimbursement for lab tests on improperly stored specimens that Defendants knew did not provide accurate and reliable results. (Doc. 57, ¶¶ 111–35, 211–18.) And Defendants billed the Government for tests using procedures that were not pre-approved or validated, again resulting in questionable accuracy. (*Id.* ¶¶ 111–35, 211–18, 109–223.) These CLIA violations weren't "minor" or "garden-variety," they go to the heart of what the Government is paying for—reliable test results that can be used to treat patients. (*See id.* ¶¶ 259–61.) The accuracy of test results certainly has a "natural tendency" to affect payment. *See Escobar*, 136 S. Ct. at 2001–

02. And Defendants' own actions show they believe these violations are material—in one instance, DaVita refunded money to the Government upon learning they were using the wrong test tubes. (*See* Doc. 57, ¶ 206.) Relators have plausibly alleged these violations are material. *See United States v. Crumb*, No. 15-0655-WS-N, 2016 WL 4480690, at *24 (S.D. Ala. Aug. 24, 2016).

Next is the "knowingly" requirement. *See Escobar*, 136 S. Ct. at 1999. Under the implied false certification theory, the question is whether Defendants knowingly failed to disclose their noncompliance with regulatory requirements. *See id.* at 1995. The FCA doesn't punish "honest mistakes" or "mere negligence"—but it doesn't protect struthious defendants who bury their heads in the sand and fail to make simple inquiries. *Urquilla-Diaz v. Kaplan Univ.*, 780 F.3d 1039, 1058 (11th Cir. 2015) (quotation marks and citations omitted). Relators allege: they expressed concerns to senior leadership about specimen stability and testing validation many times; West Coast providers using DaVita's labs repeatedly complained of unstable results; and Defendants knew or should have known they were performing modified tests. (Doc. 57, ¶¶ 248–58.) Relators also claim Defendants had actual knowledge it was disregarding material statutory regulations. (*Id.* ¶ 247.) So Relators plausibly alleged Defendants knowingly failed to disclose noncompliance with regulations and have stated a claim under the implied false certification theory. [2] *See Escobar*, 136 S. Ct. at 1995.

[2] Because Relators plausibly stated claims under the implied false certification theory, the Court will not discuss Defendants' liability arguments under other theories for Counts I and II. (*See* Doc. 74, pp. 14–15, 22.)

B. Conspiracy Claim (Count III)

For an FCA conspiracy claim, Relators must allege: "(1) that the defendant conspired with one or more persons to get a false or fraudulent claim paid by the United States; (2) that one or more of the conspirators performed any act to effect the object of the conspiracy; and (3) that the United States suffered damages as a result of the false or fraudulent claim." *Corsello v. Lincare, Inc.*, 428 F.3d 1008, 1014 (11th Cir. 2005) (quotation marks and citations omitted). "Conspire" requires a "meeting of the minds" to "defraud the Government." *U.S. ex rel. Stepe v. RS Compounding LLC,* 304 F. Supp. 3d 1216, 1227 (M.D. Fla. 2018) (quotation marks and citation omitted). Defendants argue Relators failed to plead an agreement between Defendants with the particularity required by Rule 9(b). (Doc. 74, pp. 23–25.)

Not so. Relators claim Defendants agreed to use Total Renal and DVA, in Florida, to provide lab services for DaVita's nationwide network to take advantage of tax breaks, despite knowing this would require lengthy cross-country transport of specimens for testing. (Doc. 57, ¶¶ 10–12, 15, 253.) And Relators allege Defendants have a unity of ownership and share in profits—thus a shared motivation for their regulatory shortcuts. (*Id.* ¶ 15.) Defendants also agreed to falsely certify compliance with federal regulations and to omit and misrepresent critical qualifying information, to receive reimbursement for unreliable tests. (*Id.* ¶ 314.) Finally, Relators detailed many instances where Defendants submitted specific false claims to the Government, listing which lab performed the test, which test was done, when the test was done, and how much

Defendants billed the Government. (*See id.* ¶¶ 130–134, 141–63, 171–204.)

Relators' allegations are not conclusory—they plausibly alleged particular facts showing an agreement among the Defendants to submit false claims to the Government, so the conspiracy claim stands. *See United States v. Pub. Warehousing Co. K.S.C.*, 242 F. Supp. 3d 1351, 1359 (N.D. Ga. 2017). Whether they can prove it is for another day.

C. "Reverse" FCA Claim (Count IV)

A "reverse" FCA claim arises when a defendant makes a knowing and material false statement "for the purpose to conceal, avoid, or decrease an obligation to pay money to the government." *U.S. ex rel. Matheny v. Medco Health Sols., Inc.*, 671 F.3d 1217, 1222 (11th Cir. 2012). Relators argue Defendants had a duty, by statute, to return the Government's Medicare payments for the inaccurate and unreliable tests they performed in violation of CLIA regulations. (Doc. 79, pp. 26–27; *see also* Doc. 1, ¶¶ 318–322); 42 U.S.C. § 1320a-7k(d). Defendants argue Relators' "reverse" FCA claim fails because "Relators causes of action for presenting false claims and submitting false statements fail as a matter of law." (Doc. 74, p. 25.) But the Court found these claims did not fail as a matter of law—so Defendants' arguments here are unavailing. *See supra* Section III.A.

D. Retaliation (Counts V and VI)

To plead FCA retaliation, Relators must allege they were "'discriminated against in the terms and conditions of [their] employment' for engaging in protected activity." *United States v. HPC Healthcare, Inc.*, 723 F. App'x 783, 791–92 (11th Cir. 2018) (quoting 31 U.S.C. § 3730(h)(1)). At one time, an employee had to show their actions raised the "distinct possibility" of FCA litigation. *See U.S. ex rel. Sanchez v. Lymphatx, Inc.*, 596 F.3d

1300, 1303–04 (11th Cir. 2010) (quoting *Childree v. UAP/GA AG Chem., Inc.*, 92 F.3d 1140, 1146 (11th Cir. 1996)). Amendments in 2009, however, broadened protected activities to include "other efforts to stop 1 or more violations of this subchapter." 31 U.S.C. § 3730(h)(1); *see also Sanchez*, 596 F.3d at 1303 n.5 (11th Cir. 2010). Protected conduct now includes "steps taken to remedy [FCA violations] through other means, such as by internal reporting to a supervisor or compliance department, or refusing to participate in unlawful activity." *Farnsworth v. HCA, Inc.*, No. 8:15-CV-65-T-24-MAP, 2015 WL 3453621, at *3 (M.D. Fla. May 29, 2015) (citations omitted).

Defendants argue Relators failed to show they were engaged in protected conduct because they didn't warn Defendants' of a possible *qui tam* action or threaten to report them for fraud. (Doc. 74, pp. 26–28.) But this is no longer required for an FCA retaliation claim. *See* 31 U.S.C. § 3730(h)(1); *Farnsworth*, 2015 WL 3453621, at *3; *Arthurs v. Glob. TPA LLC*, 208 F. Supp. 3d 1260, 1265 (M.D. Fla. 2015). The question is: did Relators try to stop one or more FCA violations? *See* 31 U.S.C. § 3730(h)(1). As alleged, they did.

Relators allege Holland notified his supervisors of Defendants' fraudulent billing for inaccurate and invalidated tests, even convincing Defendants to refund money to the Government in one case. (Doc. 57, ¶¶ 265–80.) They allege Taylor saw firsthand how Holland was treated after raising CLIA violations and expressed her discontent with his treatment to two higher-ups at DaVita, Dr. Van Wyck and Ms. Alpizar. (*Id.* ¶¶ 281–82.) She also expressed "serious concerns" about Defendants' medical technologist and clinicians' requests to change lab results. (*Id.* ¶ 282.) Later, Taylor expressed concern with

DaVita's CLIA compliance and method validation for peritoneal dialysate testing to her superiors. (*Id.* ¶¶ 287–291.) A reasonable inference from these allegations is that both Relators acted to prevent false claims from being filed with the Government—protected activities under the FCA. *See Arthurs*, 208 F. Supp. 3d at 1267 (voicing concerns to superiors about marketing regulation violations is a protected activity); *cf. Farnsworth*, 2015 WL 3453621, at *7 (dismissing retaliation claim where the plaintiff "set[] forth no allegations that she did anything to oppose such [fraudulent] practices or inform her superiors about them").

Defendants also argue Relators fail to show a causal connection between the protected activities and their later adverse employment actions. (Doc. 74, pp. 28–29.) Relators must establish their protected activities were a but-for cause of the retaliatory actions by their employers. *See Nesbitt v. Candler Cty.*, 945 F.3d 1355, 1359 (11th Cir. 2020). An employee suffers a retaliatory action by their employer if they are "discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment." 31 U.S.C. § 3730(h)(1).

Relators allege that shortly after uncovering faulty test procedures in February 2017, Holland was forced to resign as DaVita's CLIA Medical Director, was ostracized by his supervisor, given a written warning, issued a punishing Corrective Action Plan, and eventually terminated on May 25, 2017. (*See* Doc. 57, ¶¶ 205, 266–77.) Similarly, Taylor was forced to submit her letter of resignation just one week after raising concerns with her superiors, and even after she had agreed to resign, Defendants continued to harass

her by giving her a verbal warning and Corrective Action Plan, requiring all conversations with her supervisor to be witnessed and later memorialized, and requiring her to remain on-call but not come to the lab or attend any meetings until her employment ended. (*Id.* ¶¶ 285–86, 294.) Relators have provided sufficient factual allegations for the Court to plausibly infer their protected activities were a but-for cause of Defendants' retaliatory actions and their terminations. The close temporal proximity between events, the attempts to blame Relators for the compliance issues they uncovered, and the similarity between the way both Relators were treated after raising compliance concerns all leads to the reasonable inference that Relators were harassed and terminated for their efforts to oppose Defendants' FCA violations. (*See id.* ¶¶ 265–296); *see also U.S. ex rel. Aquino v. Univ. of Miami*, 250 F. Supp. 3d 1319, 1336–37 (S.D. Fla. 2017). So Relators have each stated claims for retaliation under the FCA.

IV. CONCLUSION

It is **ORDERED AND ADJUDGED** that Defendants' Motion to Dismiss (Doc. 74) is **DENIED.**

DONE AND ORDERED in Chambers in Orlando, Florida, on June 24, 2020.

ROY B. DALTON JR.
United States District Judge

Copies to:
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